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**Subject:** NEWS UPDATES: ACC Presses NAS Committee To Recommend Standard IRIS Procedures (Inside EPA)  
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## ACC Presses NAS Committee To Recommend Standard IRIS Procedures

Posted: September 17, 2012

The American Chemistry Council (ACC) is pressing the new National Academy of Sciences (NAS) panel that is reviewing EPA's Integrated Risk Information System (IRIS) program to recommend standardized methods of data evaluation and selection, and greater inclusion of industry in its assessment process.

In a Sept. 13 letter to NAS staff, ACC said EPA should develop "a formal protocol for each IRIS assessment that should include the literature search strategy and study inclusion/exclusion criteria, . . . develop and follow a transparent, systematic approach when evaluating each individual study for quality, reliability and relevance. Standard evaluation procedures could be developed for each type of study generally evaluated by the IRIS program (including in vivo, in vitro and epidemiological studies)." *The letter is available on [InsideEPA.com](#). See page 2 for details (Doc. ID: [2410312](#))*

ACC sent its letter ahead of the first public meeting of the new NAS Committee to Review the IRIS Process, which is taking place in Washington, DC, Sept. 17-18.

Funded by EPA, the committee's creation follows report language attached to EPA's fiscal year 2012 budget, which requested the review of up to three draft IRIS assessments released in 2012, including the draft arsenic assessment. NAS staff later convinced members of the appropriations committees to allow NAS to instead review the arsenic assessment and perform a review of the overall IRIS process instead of additional individual assessments.

The congressional budget language and new NAS project follow the Academies' critical review of EPA's draft IRIS assessment of formaldehyde, released in the spring of 2011. Since then, EPA's IRIS program has come under increasingly stringent observation from Congress and industry, which have urged the agency to rapidly adopt advice from that report.

ACC's Sept. 13 letter to NAS staff addresses many of the same concerns that the group has brought to EPA for many months. In addition to calling for standardized protocols, it also urges EPA adopt a standardized weight-of-evidence (WoE) method for assessing the data relevant to studies the agency is considering for each assessment. ACC has pressed EPA to adopt a standard framework or tool for this purpose for some time, and IRIS leaders have promised to hold a public WoE workshop to address various tools that IRIS could use for this purpose. However, a date has yet to be announced for this workshop. NAS panel chairman Jonathan Samet said the panel will also hold a public workshop in March.

IRIS leaders, including Vincent Cogliano, the program's acting director, have pressed ACC and other stakeholders

to remain patient while staff work to address the Academies' concerns with the program. Cogliano has reminded industry leaders that the formaldehyde report acknowledges that such changes take place over time, and points to the two most recently released draft IRIS assessments as examples of iterative improvement. The most recent drafts include new preambles explaining EPA and IRIS policies and new graphics intended to reduce unnecessary text while clarifying the document.

ACC staff have acknowledged EPA's changes, but add that there is more that EPA should do, and the group's latest letter reiterates that point.

But an agency source says IRIS officials do not want to make changes that would be at cross-purposes to recommendations EPA staff expect to receive from the new NAS committee. Cogliano and the new director of EPA's National Center for Environmental Assessment, Kenneth Olden, addressed the new committee Sept. 17, discussing recent and future anticipated changes to IRIS.

**In its letter, ACC also describes two new projects designed to provide more information** about data evaluation procedures and WoE tools, which it indicates will be provided to EPA and the NAS committee upon completion. ACC explains that it has "sponsored a project that considers and summarizes data evaluation procedures used by various organizations" including several EPA offices, for *in vitro* and *in vivo* studies.

"Over the next few months, [ACC's Center for Advancing Risk Assessment Science and Policy (ARASP)] will synthesize the findings and develop a white paper and manuscript, which will highlight the best practices in the field today. In addition, ARASP is sponsoring a project, slated for completion this fall, which summarizes the various WoE frameworks relevant to chemical risk assessment. The findings of this WoE project will be synthesized into a white paper and manuscript that will also highlight the best practices in the field today."

ACC also presses for greater inclusion of industry scientists in the development of IRIS assessments. The latest letter reiterates industry concerns that their expertise is ignored in the drafting of IRIS assessments, and that industry scientists are excluded from peer review panels of these assessments due to conflict of interest concerns.

"As part of an early engagement process EPA could distribute an overarching plan for conducting IRIS assessment to stakeholders. This plan could include the key points EPA wants to address in the assessment and would describe the data acquisition plan, data evaluation procedures, the methods to be used for dose response, and the frameworks for evaluating [mode of action, or how a chemical causes health effects] and WoE," according to the ACC letter. "Incorporating more information from data generators, experts, and diverse stakeholders at the outset of an assessment will lessen the need for multiple revisions of an assessment."

ACC also reminds NAS of its concern that "peer reviewers should be selected to serve on peer review committees based upon their expertise appropriate to the subject matter under review," regardless of their affiliation, and cites NAS' policies for forming its own committees. -- *Maria Hegstad*  
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